



**Swiss TPH Summer Symposium 2018**  
***Clinical Research in Resource Limited Settings:  
Mission Impossible or Role Model for Future Drug Development***



**The Partnership Approach:  
Industry Perspective**  
***Luc Kuykens, Head, Global Health Programs***

# Sanofi's Commitment to Global Health

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**We decided to contribute to better access to healthcare in specific therapeutic areas for poorly served populations, in low and middle income countries**



## **INFECTIOUS DISEASES**

- Neglected tropical diseases (e.g. Human African Trypanosomiasis, Leishmaniasis)
- Malaria
- Tuberculosis



## **NON-COMMUNICABLE DISEASES**

- Diabetes
- Cardiovascular diseases
- Mental health
- Epilepsy

# Definition of PPP's

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- A collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour <sup>(1)</sup>
- Common Characteristics:
  - Voluntary
  - Long-term contracts
  - Common purpose
  - Shared risks, responsibilities, resources, competencies and benefits

(1) Buse, K. and G. Walt, "Global Public Private Partnerships for Health: Part I - a new development in health?" Bulletin of the World Health Organization, Volume 78 (4) 2000.

# Types of PPP's industry is involved in

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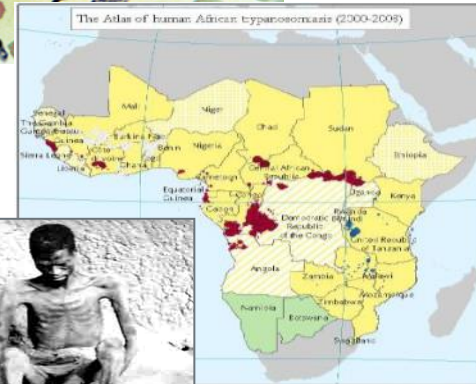
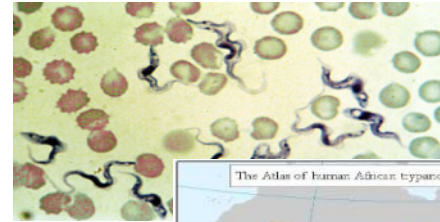
**Product-based PPPs:** such as drug donation programs in the treatment of some condition for which there is limited effective demand, due to lack of willingness or ability to pay

**Product-development PPPs:** usually require the public sector to assume a number of risks associated with product discovery, development and/or commercialization for which the government(s) or other funders provide some subsidies.

**The issues-based PPPs:** often disease driven, such as the Malaria Vaccine Initiative, the Roll Back Malaria Global Partnership or the Stop TB Initiative.

# Human African Trypanosomiasis

- **HAT is a neglected and rare tropical disease**
  - Affects remote areas of sub-Saharan African countries
  - Caused mainly by *Trypanosoma brucei gambiense*,
  - Transmitted through the bite of tsetse fly
  - Less than 2500 new cases recorded in 2016
  - WHO roadmap target for HAT: elimination in 2020 and eradication in 2030
- **Two clinical disease stages**
  - Stage 1 (early stage): haemo-lymphatic, asymptomatic stage (~ 2 years)
    - symptoms: malaise, headache, fever, peripheral oedema
    - difficult to diagnose but invariably evolves into stage 2
  - Stage 2 (late stage) : meningo-encephalic stage, rapid evolution (~ 6 months)
    - symptoms: severe headaches, behavioural changes, disorientation, psychosis and the characteristic sleep disorders then coma and death



# Sanofi's participation in multiple PPP's for HAT

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**Product-based PPPs:** long standing partnership between Sanofi, Bayer and WHO for HAT drug donation programs (since 2001), but also in support of national HAT control programs

**Product-development PPPs:** collaboration with DNDi since 2009

**Broad NTD PPP:** in 2012, pharmaceutical companies, donors, endemic countries and non-government organizations came together to sign the London Declaration on Neglected Tropical Diseases. Together, they committed to control, eliminate or eradicate 10 neglected tropical diseases by 2020

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# HAT Program History

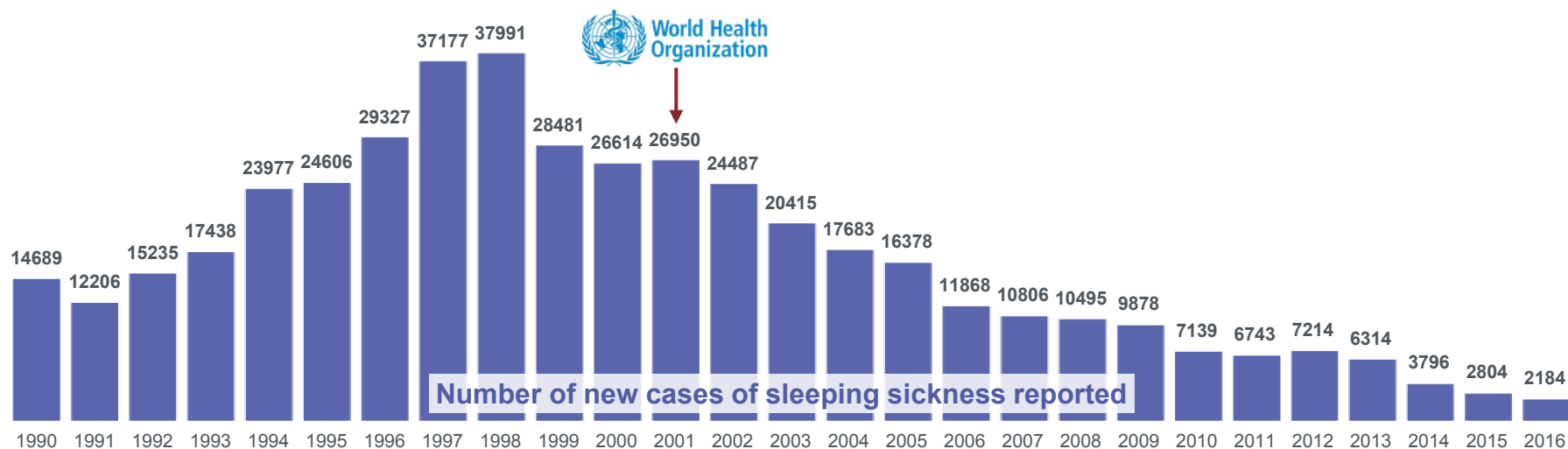
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- **Partnership with WHO since 2001:** initially to support WHO to face an outbreak of HAT. Sanofi is the MAH of the drugs for treating the disease (at that time pentamidine, eflornithine and melarsoprol). Commitment to continue manufacturing and supplying for HAT, plus funds.
- **In 2005** creation of WHO NTDs Department
- **2006-2011-2016** WHO partnership renewals
- **2009** partnership with DNDi for fexinidazole development
- **2012** signataire to the London declaration
- **2017** fexinidazole submission to EMA

# Impact on HAT number of cases through 2016

## A strong collaborative approach

- Partnership with the World Health Organization since 2001
- Over 40 million people screened and over 210,000 patients treated\*





# Challenges to achieving elimination

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Existing Scientific Gaps	Potential next steps
Understanding of HAT pathophysiology	Further Study of Transmission mechanisms/Animal reservoirs/Asymptomatic Carriers
Effective Therapeutic Interventions	Develop simple, easy to administer treatments, no LF staging need
Diagnostics & Surveillance	Establish more complete geographical surveillance, Screening testing (industrialization), confirmatory testing (complexity)

- Elimination as a public health problem by 2020: >2000 reported cases/yr and area at risk reporting < 1case/10,000 people/yr
- Interruption of transmission by 2030 (gambiense HAT)

# Improving treatment options

Toward elimination of the disease by 2020



Fexinidazole, a single treatment for all



No more IV, no more lumbar puncture



No need for complex healthcare infrastructures



Logistical simplification



Educational packaging centered on patients' needs



Submitted to EMA in December 2017

# Challenging Phase 3 Clinical Development



# To give you an idea of «what it took ....»

PNLTHA: > 100 people

Trained:

- Doctors : 34
- Lab tech : 36
- Nurses : 63

CATT (screening test)

**2.035.647** population  
examined ...

1700 new cases diagnosed

FPFV: Nov 18, 2012

LPLV (M18): October 17, 2016

Blind review: Dec 8, 2016

Data Base Lock: Jan 3 2017

Topline results: Jan 12, 2017



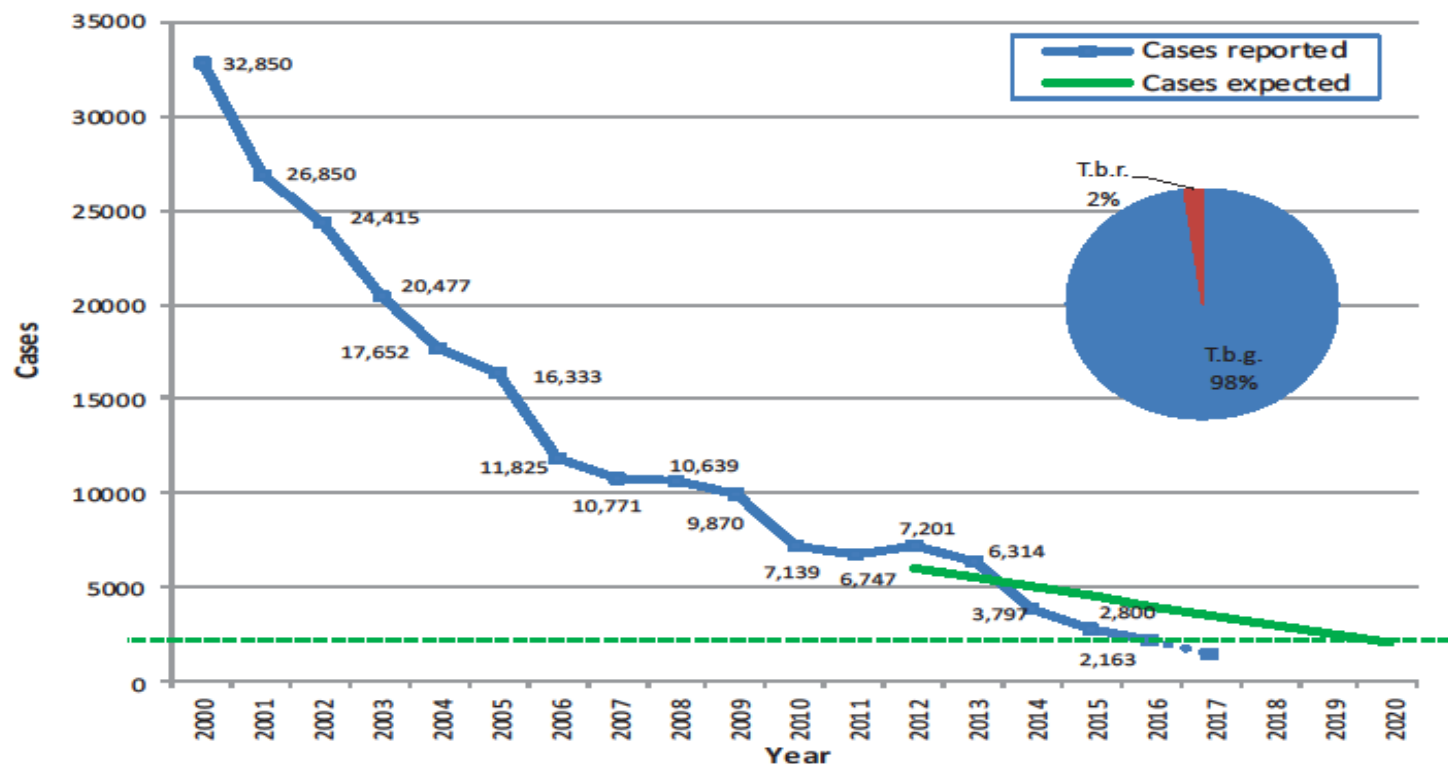
# Strengths and challenges of the HAT PPP's

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• Clear, measurable targets	↔	Eradication may remain elusive
• Long-term commitments of partners	↔	New priorities
• Continued focus on innovation	↔	Gaps in scientific knowledge
• Driver for global advocacy	↔	Donor fatigue
• Integration of national programs in health systems	↔	Vertical HAT programs

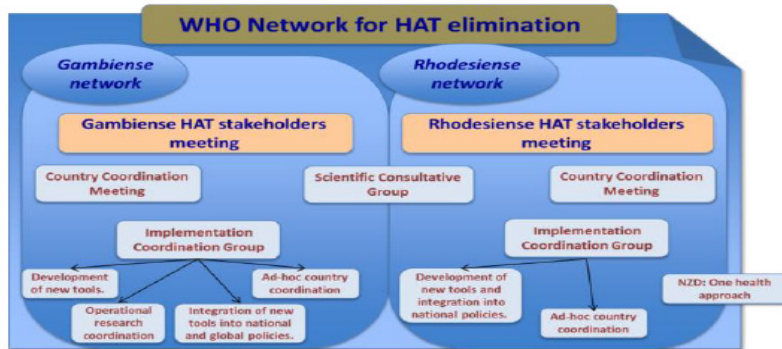
# Measuring progress towards elimination

Number of new cases reported and WHO benchmark





## WHO Network for HAT elimination







## SANOFI, A KEY ACTOR IN GLOBAL HEALTH